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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Brandon Hipsher, RAC Associate Manager, Corporate Regulatory Affairs Telephone: (574) 371-8083 Fax: (574) 372-4605
Date:	March 3, 2008
Trade Name:	*Gender Solutions*™ *Natural-Knee*® Flex System
Common Name:	Total Knee Prosthesis
Classification Name and Reference:	Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis 21 CFR § 888.3560 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 21 CFR § 888.3565 Knee joint patellofemoral polymer/metal semiconstrained cemented prosthesis 21 CFR § 888.3540
Predicate Devices:	*Gender Solutions Natural-Knee* Flex System, manufactured by Zimmer, Inc., K070214, cleared March 16, 2007. *Zimmer* Patellofemoral Joint Prosthesis, manufactured by Zimmer, Inc., K070695, cleared June 7, 2007.
Device Description:	The *Gender Solutions Natural-Knee* Flex (N-K Flex) components are semiconstrained, nonlinked condylar knee prosthesis that are designed to have a maximum active flexion of 155 degrees. The N-K Flex femoral provides increased flexion capability

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for patients who have both the flexibility and desire to increase their flexion range.

Intended Use:

N-K Flex System:

- Components with *CSTi* porous coating are indicated for uncemented or cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).

- Components without *CSTi* porous coating are indicated for cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments with conditions of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD), correctable varus-valgus deformity and moderate flexion contracture, or failed previous surgery where pain, deformity or dysfunction persists.

Comparison to Predicate Device:

Except for dimensional and material modifications, the subject components are identical to the predicate device.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Mechanical testing of the subject devices demonstrates that they are substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer, Inc.
% Mr. Brandon Hipsher
P.O. Box 708
Warsaw, Indiana 46581-0708

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Re: K073286
Trade/Device Name: *Gender Solutions™ Natural-Knee®* Flex System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prothesis
Regulatory Class: II
Product Code: JWH, MBH, KRR
Dated: March 3, 2008
Received: March 5, 2008

Dear Mr. Hipsher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073286

Device Name:
Gender Solutions™ *Natural-Knee*® Flex System

Indications for Use:
Gender Solutions™ *Natural-Knee*® Flex System:

- Components with *CSTi* porous coating are indicated for uncemented or cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).
- Components without *CSTi* are indicated for cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments with conditions of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD), correctable varus-valgus deformity and moderate flexion contracture, or failed previous surgery where pain, deformity or dysfunction persists.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073286